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FACT SHEET
KNOWLEDGE • RESOURCES • TRAINING

CLIA Program & Medicare Lab Services

What's Changed?

- Added information about sanctions (page 3)
- Added information about fees (page 5)

Substantive content changes are in dark red.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

Through the Clinical Laboratory Improvement Amendments (CLIA) Program, CMS regulates all lab testing (with some specific exceptions and state exemptions) done on humans in the U.S. to ensure accurate, reliable, and timely patient test results.

According to 42 CFR 493.2, CLIA applies to all labs examining "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."

CLIA requires labs meet applicable federal regulations. They must have a current CLIA certificate, including labs that don't file Medicare claims. CLIA requirements also apply to labs in physicians' offices.

CLIA Research

CLIA regulates research testing for returned patient-specific results. CLIA doesn't apply when a statistical research center keeps patient-specific test results for possible trials, studies, or experiments, and the entity doesn't report patient-specific results.

CLIA Agency Administration Responsibilities

Federal Agency	Responsibilities
CMS	• Approves and reapproves private accreditation organizations doing inspections • Approves state exemptions • Collects user fees • Inspects and enforces regulatory compliance • Issues lab certificates • Monitors lab proficiency testing (PT) performance and approves PT programs • Develops, publishes, and implements CLIA rules and regulations
FDA	• Categorizes tests based on complexity • Reviews requests for CLIA Waiver categorization by application • Develops CLIA complexity categorization rules and guidance
CDC	• Performs lab quality improvement studies • Develops and distributes professional information and educational resources • Develops technical standards and lab practice guidelines, including cytology guidelines • Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC) • Monitors PT practices • Provides analysis, research, and technical help

Fees from regulated facilities cover all CLIA Program administration costs, including certificates and surveys.

Getting CLIA Certification

To get CLIA certification, labs must:

- Complete the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification Form (CMS-116) and send to their CLIA state agency contact. See the Quick Start Guide for more information.
- Pay certification fees. Annual testing volume and scope determine moderate and high complexity labs' fees. Additional fees may apply.
- Be surveyed, if applicable.
- Meet CLIA certification requirements.

International Labs

If your lab is outside the U.S. (and its territories) and seeking CLIA certification, contact CLIA-IOIntake@cms.hhs.gov before completing Form CMS-116.

Lab Certificates

The CLIA Program grants 5 types of lab certificates.

Certificate of Waiver

The Certificate of Waiver (CoW) allows labs to do tests the FDA categorizes as waived tests, including:

- Certain glucose and cholesterol testing methods
- Fecal occult blood tests
- Some pregnancy tests
- Some urine tests

Labs that do **only** waived testing must:

- Enroll in the CLIA Program
- Pay applicable certificate fees every 2 years
- Follow manufacturers' test instructions

Labs with a CoW don't get surveyed every 2 years. Lab surveys happen if:

- There's a complaint
- The testing is beyond the certificate's scope
- There's risk of harm from inaccurate testing
- There's a need to collect information about waived tests

See Categorization of Tests for CLIA-waived tests information.

Note: New alternative sanctions have been added and can also include: civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite state monitoring.

What are Waived Tests?

The FDA categorizes a test as waived if it's determined to be simple with low-risk of an incorrect result or with no reasonable risk of harm. Labs with a different certificate type can do waived tests without getting a separate CoW.

Certificate for Provider-Performed Microscopy Procedures

The Provider-Performed Microscopy Procedures (PPM) certificate is a subset of moderate complexity tests and a unique lab classification and certification where a physician, mid-level practitioner (under supervision if state law requires), or dentist provides **only** certain PPM procedures and waived tests during a patient's visit.

A PPM is a moderate complexity test using a bright-field or phase-contrast microscope (for example, urine sediment exams or potassium hydroxide (KOH) preparations).

A physician, mid-level practitioner (under supervision if state law requires), or dentist must personally perform the specimen procedures during the visit.

Labs with a PPM certificate don't get surveyed every 2 years. Lab surveys happen if:

- There's a complaint
- The testing is beyond the certificate's scope
- There's risk of harm from inaccurate testing
- There's a need to collect PPM information

Certificate of Registration

Labs must get a Certificate of Registration (CoR) before applying for a Certificate of Compliance (CoC) or Certificate of Accreditation (CoA). A CoR is temporary and allows a lab to perform nonwaived moderate and high complexity tests until it gets surveyed to verify it meets CLIA regulations. A CoR is valid for only 2 years while the lab applies for the CoC or CoA.

Certificate of Compliance

A lab gets a CoC after an on-site survey finds it meets all applicable CLIA regulations. Surveys happen every 2 years at CoC labs doing nonwaived moderate and high complexity testing. The surveys:

- Help labs improve patient care through education
- Emphasize requirements directly impacting its test performance quality
- Determine labs' regulatory compliance

The surveyor decides whether labs meet CLIA regulations by:

- Interviewing personnel
- Observing current practices
- Reviewing relevant records

Note: If it's necessary to conduct a complaint investigation, or subsequent PT failure review, additional fees may apply to the lab.

Certificate of Accreditation

Labs that do nonwaived moderate and high complexity tests get CoAs when they meet the standards of an accreditation organization (AO) that we approve. An AO inspects labs once every 2 years.

We do a validation survey on a representative sample of accredited labs, or we may do a complaint survey after getting substantial non-compliance allegations.

There are 7 CMS-approved AOs, and we do an annual validation survey of each one. For approval, an AO's standards must meet or exceed CLIA regulatory requirements. Every 6 years or sooner, each organization reapplies for continued authority to ensure its standards meet or exceed CLIA's requirements.

Laboratory Certificate Fees

There are fees for:

- Revised and replacement certificates
- CoCs, CoAs, CoWs, and PPMs
- Approved state lab programs

They cover the costs of:

- Issuance
- Renewal
- Change in certificate type
- Reinstatement of a terminated certificate with a gap in service
- Other direct administrative activities

CLIA Proficiency Testing

Labs doing moderate and high complexity testing must participate in PT for certain tests. PT offers each lab doing nonwaived tests a way to measure performance and verify accuracy and reliability.

An HHS-approved PT program sends labs a set of PT samples 3 times each year. Labs test the PT samples the same way as patient specimens and report the results to the PT program. The PT program grades the results and returns the scores to the labs, so they know how accurately they tested. CMS reapproves PT programs annually. Proficiency Testing Programs has more information.

Don't refer PT samples to another lab for analysis, even if it's common practice for patient specimens.

Test Categorization

The FDA categorizes each test based on complexity. Use the CLIA database to search by test system name, analyte name, complexity, specialty, and effective date.

The FDA categorizes tests into these complexity levels:

- Waived complexity
- Moderate complexity
- High complexity

When categorizing a test, the FDA considers:

- Test knowledge needed
- Test training and experience needed
- Reagents and materials preparation
- Characteristics of operational steps
- Calibration, quality control, and PT materials
- Test system troubleshooting and equipment maintenance
- Interpretation and judgment needed

More complicated tests require stricter CLIA quality standards requirements, personnel qualifications, and responsibilities.

Medicare Lab Services

Include your unique CLIA number on all lab services claims. This 10-character alpha-numeric code identifies and tracks your lab's history. Use this number when contacting your state agency or us.

We cover lab services and other diagnostic tests, including materials and technician services, when:

- A treating physician or qualified non-physician practitioner orders or refers the services or tests
- Services are medically reasonable and necessary and meet all CLIA regulations

Clinical Labs Center has more information on lab services payment and other diagnostic tests.

Resources

- CDC CLIA
- CLIA Brochures
- CLIA FAQs
- CLIA Regulations and Federal Register Documents
- Clinical Laboratory Fee Schedule
- CMS CLIA
- FDA CLIA
- Medicare Claims Processing Manual, Chapter 16, section 70